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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/771,263 | 01/26/2001 | Gale Arthur Granger | IRVN-005CIP | 7988 |

24353 7590 07/12/2005

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| EXAMINER |
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YAEN, CHRISTOPHER H

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| ART UNIT | PAPER NUMBER |
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1643

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,263

Applicant(s)

GRANGER ET AL.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7-14,18-24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,7-14,18-24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Granger *et al*

1. The amendment filed 4/19/2005 is acknowledged and entered into the record. Accordingly, claims 1,6,15-17, and 25 are canceled without prejudice or disclaimer, and claims 27-31 are newly added.
2. Claims 2-5,7-14,18-24, and 26-31 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection Withdrawn - 35 USC § 112, 2nd paragraph

4. The rejection of claims 2-5,7-14,17-22, and 23 under 35 USC § 112, 2nd paragraph as being indefinite is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed 4/19/2005.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 2-5, 8-10,13, 19-20 and 24 under 35 USC § 102 (b) as being anticipated by Kohler *et al* is maintained for the reasons of record. Applicant arguments are substantially similar to those previously presented. Applicant has not provided further indication or arguments to distinguish why the claimed invention from that taught and anticipated by Kohler *et al*. Specifically, applicant contends that the donor lymphocytes are haploidentical to the subject being treated and that the instantly claimed invention is drawn to donors that are "unrelated" to the subject being treated.

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Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

As previously stated, Kohler *et al* teach a "pool" of alloactivated peripheral blood lymphocytes (PBL) that comprises a haploidentical lymphocytoid from a donor. Because the "pool" of PBLs are from 10 unrelated donors and because the exposure of at least two of the unrelated or allogeneic populations of lymphocytes within the pool initiates the transformation of the lymphocytes (i.e. alloactivation), the composition taught by Kohler *et al* anticipates claims that read on alloactivated lymphocytes from unrelated donors. The claims do not specifically preclude the ^{at} ~~the~~ all the donor lymphocytes populations being unrelated.

Therefore, the rejection of claims under 35 USC 102(b) is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

6. The rejection of claims 2-4, 7, 9-10, 13, 17-24, 26 and now newly added claims 27-30 under 35 USC § 103(a) as being obvious over Kruse *et al* is maintained for the reasons of record. Applicant argues that Kruse *et al* do not teach the claimed inventions. Specifically, applicant argues that the cell population was inactivated and "there were never any more than one responder population to become alloactivated." Applicant also argues that T lymphocytes tested were syngeneic to the subject being tested, not allogeneic and further concludes that it was doubtful whether there would be any tumor antigen left in association with the anti-9L CTLs after CTLs had lysed the 9L

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tumor cells used in culture as stimulators. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In the instant case, applicant provides arguments which are at best speculative. Applicant has not provided any objective evidence that the cell population was in fact inactivate or that wasn't more than one responder population as claimed. Moreover, applicant's assertions that the remnants of the tumor antigen following activation are pure speculation without any objective evidence. Finally, the cells administered to the rats were in fact allogeneic because a DA rat lymphocytes were administered to Fisher rats (F344).

Applicant additionally argues that the cell mixture, which comprises tumor cells and alloactivated T cells, administered to the subject would not have cancer prior to injection. Applicant indicates that this differs from the instantly claimed invention in that the subject would have cancer and that the inclusion of the tumor associated antigen serves the purpose of bystander antigens. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. *Kurse et al* provide a model from which the application of alloactivated T-cells can be applied to human therapy. It is apparent to the skilled artisan that the administration of live tumor cells to a subject would be counter-productive if the purpose of the administration is for the purposes of treating cancer. Thus the administration of TAAs in conjunction with the alloactivated T-cells serves the same purpose as that instantly claimed and one

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of ordinary skill in the art would be motivated and expect reasonable success in view of the teachings of Kruse *et al.*

Therefore the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

Double Patenting Rejections Maintained

7. The rejection of claims 2-5,7-14,18-24,26, and now newly added claims 27-31 under the judicially created doctrine of obvious type double patenting as being obvious over US Patents 6,203,787 and 6,207,147 is maintained for the reasons of record. Applicants have not provided any arguments or terminal disclaimer to overcome the rejection of record. Therefore the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
July 6, 2005


SHEELA HUFF
PRIMARY EXAMINER